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Dated 19 January 2001

GB0003790.3

By virtue of a direction given under Section of the Patents Act 1977, the application is proceeding in the name of

ASTRAZENECA AB,
Incorporated in Sweden,
S-151 85 Sodertalje,
Sweden

[ADP No. 07822448003]

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0003790.3 18 FEB 2000

3. Full name, address and postcode of the or of each applicant *(underline all surnames)*

AstraZeneca UK Limited
15 Stanhope Gate
London
W1Y 6LN
GB

SECTION 30 (1977 ACT) APPLICATION FILED 4/7/2000

Patents ADP number *(if you know it)*

If the applicant is a corporate body, give the country/state of its incorporation

4. Title of the invention

Medical Device

5. Name of your agent *(if you have one)*

"Address for service" in the United Kingdom to which all correspondence should be sent *(including the postcode)*

McNeight & Lawrence
Regent House, Heaton Lane
Stockport, Cheshire SK4 1BS

Patents ADP number *(if you know it)*

0001115001

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Number of earlier application	Date of filing *(day / month / year)*

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12. Name and daytime telephone number of person to contact in the United Kingdom Mr James A Robertson

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Patents Form 1/77

Medical Device

The present invention concerns safety shield systems for protecting against needle sticks.

Needle stick injuries pose a substantial threat to health since they can frequently result in the transmission of disease from one person to another. Once a needle stick injury occurs then it is typically necessary to screen the injured person for a substantial period for e.g. HIV or hepatitis infection, and it may also be necessary to restrict the type of work they do, or the people they are work with. The whole experience, even if the injured person has not been infected, is highly traumatising and extremely costly for healthcare providers. Infection is quite unacceptable if the stick injury could have been prevented in the first place. Needle stick injuries are of particular concern to healthcare professionals who are most frequently exposed to possible contamination and are in most frequent contact with infected patients. The recognition of the dangers posed by needle stick injuries has resulted in a general desire to prevent their occurrence, and various types of safety system are available which either retract the needle or shield it after use in order to minimise the possibility of needle stick injuries. The use of such safety systems is being encouraged and enforced by various pieces of "sharps" legislation in the USA, as well as by healthcare insurers and providers.

Examples of prior art safety systems include EP 0966983, the contents of which are incorporated herein in their entirety. EP 0966983 discloses a shield system for prefilled syringes, comprising an outer syringe holder and an inner shield. In use, a prefilled syringe comprising a barrel having a proximal flange, a distal needle, and containing a plunger, is inserted within the enclosure defined by the outer holder and inner shield and is held by the outer enclosure. When sufficient pressure is exerted on the holder by the syringe barrel (for example by pressure exerted on the plunger when the contents of the

syringe barrel have been completely injected) the shield is released and is urged in a distal direction by a spring located between the barrel and shield, putting the shield in an extended position and covering the needle.

However, the prior art devices, including EP 0966983, have a number of disadvantages and potential problems in their design and construction. For example, the devices of EP 0966983 are prone to accidental triggering of the shield mechanism since sufficient force (e.g. caused by accidental dropping) exerted on the syringe barrel will in turn exert sufficient force on the outer holder to trigger the shield mechanism. Also, it would appear that the insertion of a syringe into the outer holder/inner shield arrangement with sufficient force that it is retained by the holder may cause triggering of the shield mechanism. Alternatively, this possibility may be avoided by placing the syringe in the enclosure defined by the holder before engaging the shield with the holder. However, such a method of manufacture of the device is somewhat complicated and cumbersome, and would prevent the sale and distribution of the holder/shield arrangement independent of any syringe to be used with it. In addition, the actual triggering of the shield mechanism requires the discrete step of exerting a greater force on the plunger rod than that applied during injection, and is done subsequent to removal of the needle from the patient (numbered paragraph 27). This means that a potentially unacceptable period exists during which needle sticks may occur, and requires an additional step in the use of the syringe. Another disadvantage encountered is that the spring extends to cover the syringe barrel. This can be particularly problematic when injecting a patient since the contents of the syringe barrel are no longer fully visible when the spring is extended, despite the fact that it may be necessary to see them in order to ensure that a proper dosage of medicament has been administered to a patient. Similarly the extended spring makes it difficult to view any label on the syringe barrel, which may be necessary to confirm that the correct medicament was administered to a patient.

The fact that the shield mechanism, including the shield, spring, trigger mechanism and holder must all be grouped together (see for example Figure 5 of EP 0966983) means that the safety shield arrangement can be quite bulky.

It is frequently necessary when using syringes to insert the needle at a specific acute angle (for example it may be that a long solid medicament formulation must be inserted subcutaneously within narrow depth range) in order that "coring" is avoided whereby a core of tissue is cut by the needle, in turn causing tissue bruising and trauma and possibly affecting the efficacy of the injected medicament. Bulky safety shields cannot have a finger grip (flange), or at least one of useful dimensions, around the whole of their perimeter whilst still allowing for a sufficiently acute (i.e. shallow) angle to be achieved between the needle and the patient's skin, and so instead are typically provided with laterally-extending flanges radially opposite one another. They are typically manipulated such that when the needle enters the skin the flanges are positioned such that they do not contact the skin (i.e. they are parallel to the plane of the surface of the skin). However, depressing the plunger (which may require a relatively large amount of force to be exerted in a careful and controlled manner when injecting e.g. a solid medicament formulation) can then prove to be difficult since the flanges are in an inconvenient position. Users sometimes overcome this and gain a good grip on the flanges by rotating the syringe by 90 degrees after the needle has entered the skin (i.e. so that the flanges are perpendicular to the plane of the surface of the skin). However, the large bore and sharp edges of the needle tip may cause the rotation to cut a "core" of tissue from the patient, in the same fashion as a groundsman cuts a hole on a green on a golf course.

Other safety shield arrangements include those of US 5163918, US 5201720, US 5271744, US 5855839 and those referenced by EP 0966983.

The present invention overcomes the prior art disadvantages and provides an alternative and improved safety shield system for syringes. Particular advantages of the present invention are that it is less bulky than prior art devices. that its spring does not extend substantially over the syringe barrel, that the safety shield mechanism is substantially less prone to being accidentally triggered and is not affected by attempts to force apart holder and shield for example by exerting force on the syringe barrel, and that the safety shield mechanism is activated by the movement of the plunger rather than by pressure exerted on the syringe barrel, and can be achieved as an integral part of the injection process rather than as an additional discrete step.

According to the present invention there is provided an automatically operable safety shield system for use with a syringe, said safety shield system comprising:

an inner holder having proximal and distal portions and defining an enclosure into which said syringe may be inserted;

an outer shield having proximal and distal portions, mounted outwards from said inner holder and being axially movable relative to said inner holder between retracted and extended positions;

a spring positioned between a first distal detent on said inner holder and a second distal detent on said outer shield, and urging said outer shield to its extended position;

said inner holder having at least one first opening and said outer shield having at least one first stop member, said first stop member being engageable with said first opening when said shield is in said retracted position;

said inner holder having distal to said first opening at least one first indentation, said first stop member being engageable with said first indentation when said shield is in said extended position; and

a trigger positioned within said inner holder and axially movable relative to said inner holder such that it can contact said first stop member when it is

engaged with said first opening and disengage said first stop member from said first opening, allowing said spring to move said outer shield to said extended position.

Syringes are ordinarily comprised of a generally cylindrical portion, known as a barrel, a needle or other piercing or connecting element secured to one end of the barrel, and a piston or stopper slidably positioned within the barrel. A plunger rod is typically engaged with the piston such that movement of the plunger rod causes movement of the piston. The needle may be removably secured to the barrel, or it may be permanently secured to the barrel.

The automatically operable safety shield system may additionally comprise a syringe comprising a barrel, a needle, a piston and a plunger rod movable within said barrel, said plunger rod having a protrusion, said syringe being operationally coupled to said trigger such that movement of said plunger rod protrusion to contact said trigger causes disengagement of said first stop member from said first opening, allowing said spring to move said outer shield to said extended position.

Also provided according to the present invention is an automatically operable safety shield system, comprising:

a syringe comprising a barrel, a needle, a piston and a plunger rod movable within said barrel, said plunger rod having a protrusion;

an inner holder having proximal and distal portions [illegible] which said syringe may be inserted;

an outer shield having proximal and distal portions, mounted outwards from said inner holder and being axially movable relative to said inner holder between retracted and extended positions;

a spring positioned between a first distal detent on said inner holder and a second distal detent on said outer shield, and urging said outer shield to said extended position;

said inner holder having at least one first opening and said outer shield having at least one first stop member, said first stop member being engageable with said first opening when said shield is in said retracted position;

said inner holder having distal to said first opening at least one first indentation, said first stop member being engageable with said first indentation when said shield is in said extended position; and

said syringe being operationally coupled to said inner holder and outer shield such that axial movement of said plunger rod protrusion relative to said inner holder causes said plunger rod protrusion to contact said first stop member when it is engaged with said first opening and disengage said first stop member from said first opening, allowing said spring to move said outer shield to said extended position.

Said outer shield and inner holder may have, respectively, proximal and distal abutment surfaces in opposing relationship to one another, which can engage one another to prevent movement of said outer shield beyond its extended position.

The inner holder and outer shield may be of any desired shape. For example, they may be of a generally cylindrical shape. An example of a cylinders is one having circular cross-sections (commonly referred to as a right circular cylinder). Alternatively, a cylinder may have an elliptical cross-section. This may be particularly useful in ensuring that the inner holder and outer shield cannot be put together in an incorrect arrangement.

The inner holder and outer shield may also be constructed so as to avoid their relative rotation by providing guide means for their axial movement. Guide means may take the

form of grooves in the inner holder and/or outer shield. For example, the first stop members may slide along a groove on the inner holder. Similarly, the outer shield proximal abutment surface may be guided towards the inner holder distal abutment surface by a groove on the outer shield.

All embodiment of the present invention provide the distinct advantage over the prior art of it being the movement of the plunger rod, rather than of e.g. the syringe barrel, which enables the spring to move the shield to the extended position. This is typically the position where the plunger rod is fully depressed and the contents of the syringe have been expelled and e.g. injected into a patient. The disengagement of the first stop member from the first opening may be achieved either by direct contact of a plunger rod protrusion with the first stop member, or by an indirect communication of the plunger rod protrusion with the first stop member.

Direct contact may be achieved by e.g. providing the plunger rod with a thumb stop which has an axial extension which, when the plunger rod is depressed, contacts the first stop member. Alternatively, the plunger rod may for example be provided with a thumb stop and an additional protrusion which, when the plunger rod is depressed, contacts the first stop member.

Indirect contact may be achieved by any arrangement which can communicate movement caused by the plunger rod (or plunger rod protrusion) to the first stop member. The exact nature of the arrangement will depend on the construction of the plunger rod. For example a plunger rod may have a thumb stop which, when the plunger rod is depressed, contacts a member (such as said trigger) located within the inner holder which in turn contacts the first stop member and causes its disengagement from the first opening.

The first stop member may be lockably engageable with the first indentation. It may engage the first indentation such that axial movement, both distal and proximal, of the outer shield relative to the inner holder is prevented. The inner holder first indentation may be replaced by any other arrangement or means, for example a protruding member such as an escarpment of frustoconical portion which inhibits the relative movement of the inner holder and outer shield, although the prevention of any axial movement is preferred.

The first distal detent may protrude outwardly from the inner holder, and the second distal detent may protrude inwardly from the outer shield.

The syringe may be retained within the inner holder by any appropriate means. For example, in order to ensure the correct positioning of the syringe relative to the inner holder the syringe may abut an inner holder detent, for example an upper surface of an inner holder first distal flange. It may also be advantageous to provide the inner holder with syringe engagement means for engaging and retaining the syringe. For example, the inner holder and syringe barrel may be designed so that they make an interference fit, the syringe once inserted into the inner holder only being removable with the application of substantial force, for example of at least 100N.

Thus the syringe may be axially immovable relative to the inner holder.

The use of an interference fit (also referred to as a friction fit) obviates the need for other retaining mechanisms for the syringe, for example frustoconical portions formed in the inner holder to retain the syringe within a certain area. This in turn means that the syringe need not have any flanges as are typically provided in the form of finger grips, allowing for the syringe to be of smaller dimensions than those used in prior art devices and therefore for the safety shield arrangement to be smaller. It may of course be desirable

to retain at least a small flange simply to aid in the manipulation of the syringe barrel during the manufacture of the syringe, particularly in the case of prefilled syringes.

A useful material for the construction of the inner holder and outer shield is a clear polystyrene. The syringe barrel may be constructed from polypropylene. The syringe barrel may be divided into a number of sections. For example it may comprise upper and lower portions engaging and retaining a glass section. The lower portion may engage the inner holder. The glass section may be lensed to provide a magnified view of the contents of the syringe barrel.

In the case of syringe barrels having no flanges or reduced size flanges, the inner holder may be arranged such that the inserted syringe barrel acts to minimise the possibility of accidental disengagement of the first stop member and first opening by e.g. fingers or other small objects being inserted into the inner holder, and the syringe plunger rod may have a flange with a protrusion, for example an axially protruding collar which, when the plunger rod is depressed, passes around the outside of the syringe barrel and contacts, either directly or indirectly, the first stop member to cause its disengagement.

The reduced dimensions of the inner holder and outer shield (relative to prior art shield and holder arrangements) allow for the provision of a finger grip (flange) of usable dimensions, for example extending at least 3mm, 4mm or 5mm, around the whole of the circumference of the inner holder whilst still allowing even large bore needles to be inserted into a patient at an angle which does not cause coring. This is particularly useful since it enables the user to readily hold the inner holder at a variety of positions and allows hand positions to be changed without losing the grip required for a satisfactory injection, or without necessitating rotation of the syringe and the possible coring which might occur.

The syringes used with the present invention may typically contain solid medicament formulations (also referred to as depots) to be injected subcutaneously. Such injections require that the syringe piston extends through the bore of the syringe needle to ensure that the solid medicament formulation has been wholly expelled from the syringe. The protruding piston can act to lessen the chance of needle sticks if the needle is exposed for any reason, and thus retaining the piston in its extended position by for example ensuring that the depressed plunger rod cannot be pulled back can therefore provide a useful additional safety feature.

Thus the inner body may additionally comprise a plunger rod retaining member, for example a deflectable member or members, for example a frustoconical arrangement or an escarpment, in the inner holder which allows the plunger rod to be depressed past an upper (i.e. proximal) inclined surface but which provides a lower (i.e. distal) abutment surface which prevents removal of the plunger rod.

The arrangement of the spring with the first and second distal detents of the inner holder and outer shield means that when extended the spring covers an area from the inner holder first distal detent to the outer shield second distal detent, i.e. the spring does not expand to cover the syringe barrel. Therefore, when the inner holder is made of a transparent material, it is possible even after extension of the outer shield to view the contents of the inner holder, meaning that in the case of non-solid medicament formulations the complete expulsion of the contents of the syringe may be readily confirmed at any time.

The fact that the spring does not extend to cover the syringe barrel also provides the useful advantage that the spring cannot damage the syringe barrel, such damage being a recognised problem in the prior art which frequently necessitates the use of an

additional protecting member when e.g. using a syringe having a glass barrel (see for example EP 0966983 column 7 lines 19-21).

In order to ensure that the squeezing of the shield system by a user does not prevent it from working, the inner holder may be provided with a finger grip area comprising a flange and a rigid section of the inner holder. Squeezing of this will not cause the inner dimensions of the inner holder to be reduced and therefore the safety shield system will function correctly.

The first stop member may engage an abutment surface of the first opening. The first stop member may be provided in the form of an arced flexible member extending from the outer shield, i.e. extending outwardly and then inwardly. Such an arrangement may allow for the first stop member when engaged with the abutment surface of the first opening to have the centre of its pivotal axis inwards of the point of engagement. This means that if an attempt is made, either accidentally or intentionally, to disengage the first stop member and first opening by pulling them apart, they will in fact engage one another more strongly than before and thereby resist being pulled apart. This is a feature lacking in other prior art devices which for example have flexible stop members which disengage upon the exertion of sufficient force.

The invention will be further apparent from the following description together with the drawings of the accompanying Figures which show, by way of example only, one form of safety shield and syringe arrangement. Of the Figures:

Figure 1 shows a side view of a safety shield and syringe arrangement of the invention, having an outer shield in its retracted position;

Figure 2 shows a section on line M-M of Figure 1;

Figure 3 shows a side view of the arrangement of Figure 1, having been axially rotated through 90 degrees;

Figure 4 shows a section on line N-N of Figure 3;

Figure 5 shows a side view of an inner holder;

Figure 6 shows a section on line C-C of Figure 5;

Figure 7 shows a section on line D-D of Figure 5;

Figure 8 shows a section on line E-E of Figure 5;

Figure 9 shows a cut-away view along line A-A of Figure 5;

Figure 10 shows a side view of the inner holder of Figure 5, having been axially rotated through 90 degrees;

Figure 11 shows a section on line B-B of Figure 10;

Figure 12 shows a side view of an outer shield;

Figure 13 shows a section on line K-K of Figure 12;

Figure 14 shows a cut-away view along line H-H of Figure 12;

Figure 15 shows a side view of the outer shield of Figure 5, having been axially rotated through 90 degrees;

Figure 15a shows an enlarged view of circled area L of Figure 15;

Figure 16 shows a cut-away view along line G-G of Figure 15;

Figure 17 shows a side view of a trigger;

Figure 18 shows a section on line F-F of Figure 17;

Figure 19 shows a top view of the trigger of Figure 17;

Figure 20 shows a perspective view of the safety shield and syringe arrangement of Figure 1;

Figure 21 shows a partially cut away perspective view of the safety shield and syringe arrangement of the present invention, the outer shield being its extended position;

Figure 22 shows a front view of the arrangement of Figure 1 in the extended position;

Figure 23 shows a section on line B-B of Figure 22;

Figure 24 shows a side view of the arrangement of Figure 1 in the extended position;

Figure 25 shows a section on line C-C of Figure 24;

Figure 26 shows a front view of a second safety shield and syringe arrangement prior to extension of the safety shield;

Figure 27 shows a section on line C-C of Figure 26;

Figure 28 shows a side view of the arrangement of Figure 26; and

Figure 29 shows a section on line B-B of Figure 28.

Example 1

In a first embodiment, the safety shield and syringe arrangement 10 of the present invention comprises inner holder 20, outer shield 30, metal coil spring 40, trigger 50 and syringe 60.

Inner holder 20 is constructed from clear polystyrene and is of an elongate, generally cylindrical shape, defining enclosure 70, and has inner holder proximal portion 80 and inner holder distal portion 90 and ends 100,110 defining end openings. Proximal portion 80 widens towards end 100 to form mouth 111 which in use is gripped by the hand of a user. Mouth 111 is substantially rigid such that pressure exerted by a user does not reduce its diameter and hinder the operation of the safety shield arrangement 10 by the extension of outer shield 30. Mouth 111 has radially outwardly extending flange 120 which in use acts as a finger grip, allowing easy manipulation of arrangement 10 by a user. Located at the distal end of mouth 111 are two first openings 130 radially opposite one another, and having distal surfaces defined by two first frustoconical portions 140 providing upper abutment surfaces 150 and lower inclined surfaces 160. Extending

axially distal from first frustoconical portions 140 are first grooves 145. Located in distal portion 90, axially distal from first openings 130, are two first indentations 170 with two deflectable tongues 180 extending into them in a proximal to distal direction. The distal ends 181 of tongues 180 extend radially outwards from proximal ends 182.

Axially rotated 90 degrees from first openings 130, first frustoconical portions 140 and first indentations 170 and extending distally are two second grooves 185. Located in distal portion 90 are two detents comprising two outwardly extending second frustoconical portions 190, having upper abutment surfaces 200 and lower inclined surfaces 210. Radially inwards of second frustoconical portions 190 is radially inwardly extending collar 220 which (see below) engages syringe 60. Axially distal of collar 220 is radially inwardly extending distal flange 230 having upper and lower abutment surfaces 231,232.

Outer shield 30, also constructed from clear polystyrene, is of a shape which matches that of inner holder 20 such that it is axially slidable over inner holder 20. Outer shield 30 has proximal and distal portions 240,250 and proximal and distal ends 260,270. Proximal end 260 is provided with two radially opposite inwardly extending flanges providing abutment surfaces 280 having axially extending inclined side walls 290. Abutment surfaces 280 and side walls 290 are shaped such that they are able to cover second frustoconical portions 190 with a tight fit. Proximal end 260 is also provided with two stop members 300 axially rotated 90 degrees from abutment surfaces 280. Stop members 300 comprise deflectable arms 310 generally having the shape of the perimeter of a bilaterally symmetrical trapezoid, and heads 320. The distal end of arms 310 extends inwardly and moving axially, arms 310 extend outwardly. Heads 320 extend inwardly of the proximal end of arms 310 and provide proximal abutment surfaces 330. Distal end 270 is provided with generally annular protrusion 340 providing inclined abutment

surface 350, axially distal to which extends second distal detent 360 having distal abutment surface 370.

Trigger 50 is of a generally cylindrical shape, having proximal and distal ends 380,390 and is designed to fit into mouth 111 of inner holder 20 such that it is axially slidable within mouth 111. Distal end 390 has inwardly curving neck 400.

Syringe 60 comprises generally cylindrical barrel 410 containing solid medicament formulation (not shown), having flange 420 at its proximal end and needle 430 and removable needle cover 431 at its distal end. Piston 440 is slidably positioned within barrel 410. Plunger rod 450 is engaged at one end with piston 440 and at the other end has a flange providing thumb push 460. Safety clip 470 is removably secured to the portion of plunger rod 450 exposed from barrel 410, and prevents movement of plunger rod 450.

The safety shield and syringe arrangement is constructed by first placing metal coil spring 40 within outer shield 30 such that it contacts abutment surface 360 of distal flange 370. End 110 of inner holder 20 is then gripped and slid within proximal end 260 of outer shield and slid towards distal end 270. Arms 310 and heads 320 of stop members 300 are deflected outwards as they pass over inclined surfaces 160 of frustoconical portions 140 until they have been slid past frustoconical portions 140, at which point they snap inwardly such that abutment surfaces 150,330 are opposite one another. Further sliding of inner holder 20 is prevented by end 110 contacting inclined abutment surface 350 of outer shield 30. The sliding of inner holder 20 within outer shield 30 causes spring 40 to be compressed between abutment surface 360 of outer shield 30 and lower abutment surface 232 of inner holder 20. Releasing the grip on inner holder 20 allows spring 40 to expand slightly, urging apart inner holder 20 and outer shield 30, and opposing abutment surfaces 150,330 engage one another and prevent further relative

movement of inner holder 20 and outer shield 30. The outer shield is now engaged in a retracted position.

The arrangement of arms 310 and heads 320 of stop members 300 is such that the centre of the pivotal axis of arms 310 is radially inwards of the area of contact of abutment surfaces 150,330. In contrast with prior art devices whose holder and shield parts may be disengaged by exerting sufficient force, this means that attempting to pull apart (i.e. disengage) inner holder 20 and outer shield 30 causes stop members 300 to engage inner holder 20 more substantially.

Trigger 50 is then slid into mouth 111 of inner holder 20 such that neck 400 contacts heads 320.

Syringe 60 is then inserted, needle 430 first, into mouth 111 of inner holder 20 and slid towards end 110 such that needle 430 and needle cover 431 protrude from end 110. Insertion is halted when barrel 410 contacts upper abutment surface 231 of distal flange 230. Barrel 410 of syringe 60 is constructed from polypropylene and forms an interference fit with collar 220 such that it cannot be readily removed from inner holder 20 without the exertion of substantial force. Flange 420 prevents trigger 50 from being removed from mouth 111, but does not exert any force upon trigger 50 and does not cause and movement of trigger 50 which may result in the disengagement of inner holder 20 and outer shield 30.

In use, safety clip 470 and needle cover 431 are removed from plunger rod 450, needle 430 is inserted into a patient (not shown) and thumb push 460 depressed to slide piston 440 through barrel 410 and expel solid medicament formulation (not shown) from needle 430 and to cause piston 440 to extend from needle 430. Simultaneously (i.e. not as part of a separate step), thumb push 460 enters mouth 111 and contacts trigger 50, causing

it to move axially. This axial movement of trigger 50 is hindered by heads 320, but curved neck 400 deflects heads 320 outwardly as trigger 50 moves axially. Sufficient axial movement of trigger 50 and thus outwards movement of heads 320 causes opposing abutment surfaces 150,330 to become disengaged, allowing axial movement of outer shield 30. Spring 40 urges apart inner holder 20 and outer shield 30 and as needle 430 is removed from patient 480 outer shield 30 is caused to slide over inner holder 20, covering needle 430 and preventing any possible needle sticks. During the sliding step, rotation of inner holder 20 and outer shield 30 relative to one another is prevented by grooves 145,185 guiding heads 320 of stop members 300 and second frustoconical portions 190 respectively. As needle 430 is fully removed from patient 480 heads 320 pass over inclined tongues 180 and lockably snap into first indentations 170, preventing further axial movement of inner holder 20 and outer shield 30. Simultaneously, abutment surfaces 280 and side walls 290 slide over second frustoconical portions 190 with a tight fit, abutment surfaces 280 contacting upper abutment surfaces 200, and preventing any further extension as an additional safety feature. The outer shield is now locked in an extended position. The entire operation of the safety shield and syringe arrangment 10 of the present invention can be readily achieved by a person using a single hand.

Example 2

A second embodiment is as Example 1 except that syringe barrel 410 does not have flange 420, and trigger 50 is not held in mouth 111, instead being replaced by axial extension 600 of thumb push 460. This configuration minimises the possibility of accidentally causing disengagement of opposing abutment surfaces 150,330 whilst placing syringe 60 in inner holder 20, or of otherwise accidentally causing disengagement of opposing abutment surfaces 150,330. Absent flange 420, it is also possible to reduce the diameter of mouth 111 and therefore either reduce the overall

dimensions of inner holder 20 or to extend flange 120 to allow for further improved gripping by a user.

Example 3

A third embodiment is identical to Example 1 except that mouth 111 is provided with deflectable frustoconical portions 500 (not shown) having upper (proximal) inclined surfaces 501 (not shown) and lower (distal) abutment surfaces 502 (not shown) substantially perpendicular to the axis of the inner holder. In use, as thumb push 460 enters mouth 111 (and the solid medicament formulation is expelled from needle 430 and piston 440 extends from needle 430) it deflects frustoconical portions 500 and passes beyond them, at which point they return to their original shape and present abutment surfaces 502 which oppose thumb push 460, preventing its removal from mouth 111. This means that piston 440 is locked in position extending from needle 430 such that even if outer shield 30 is removed or damaged such that needle 430 is exposed, needle sticks are substantially prevented.

Figure 1

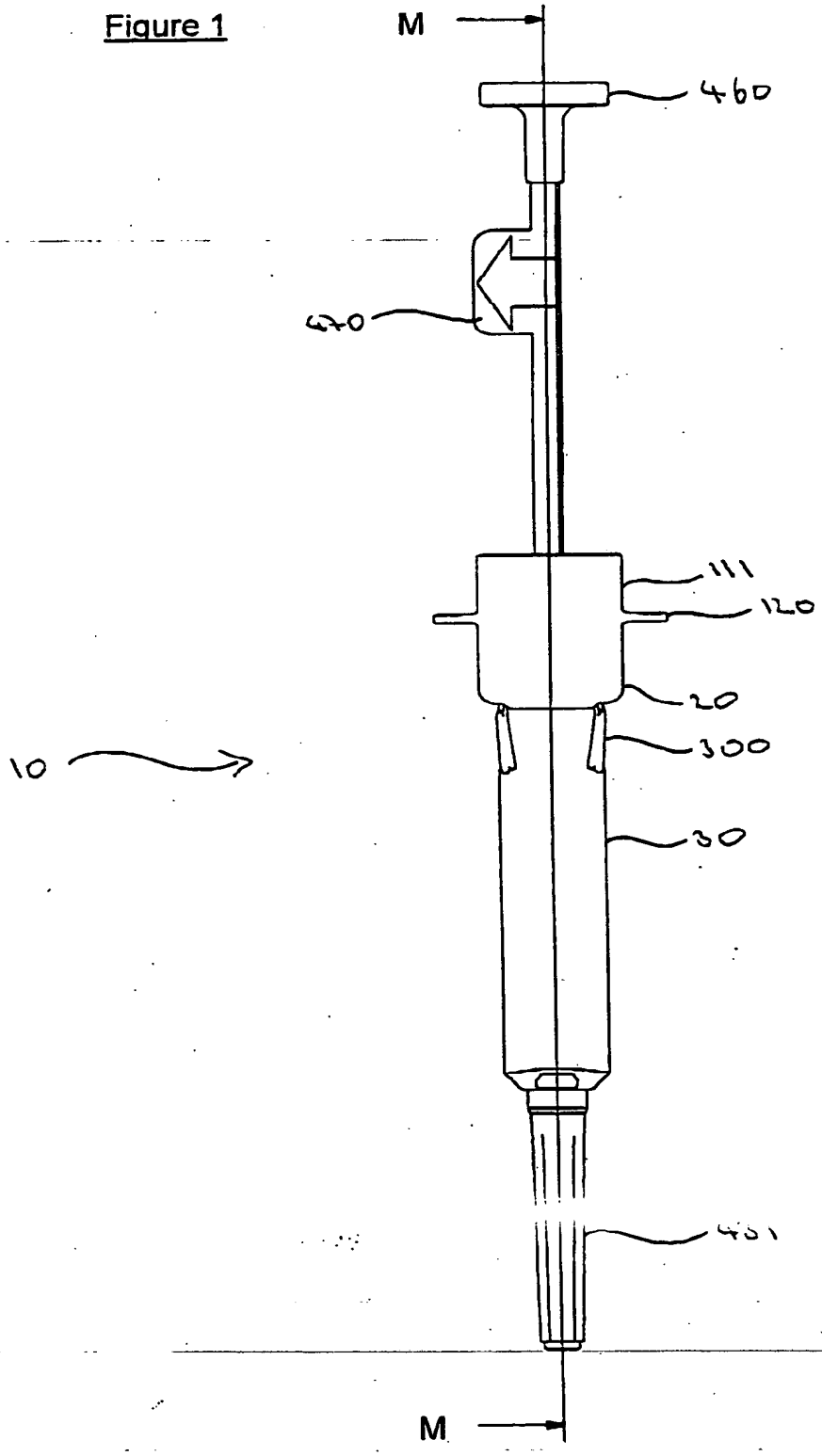

Figure 2

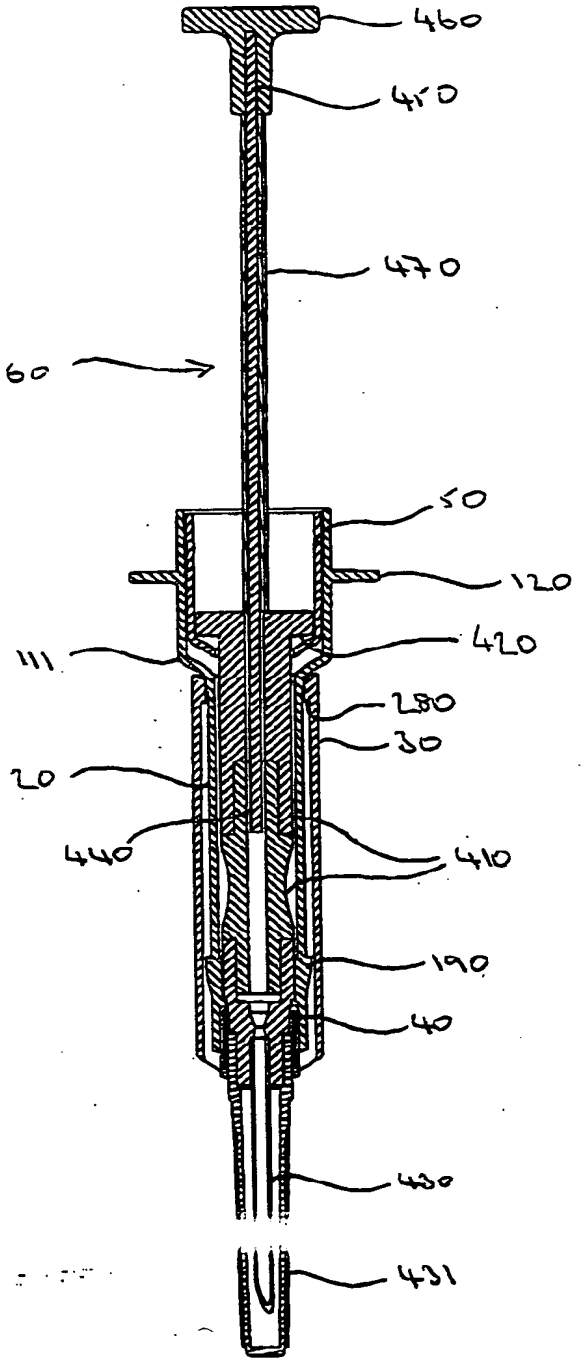

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Figure 3

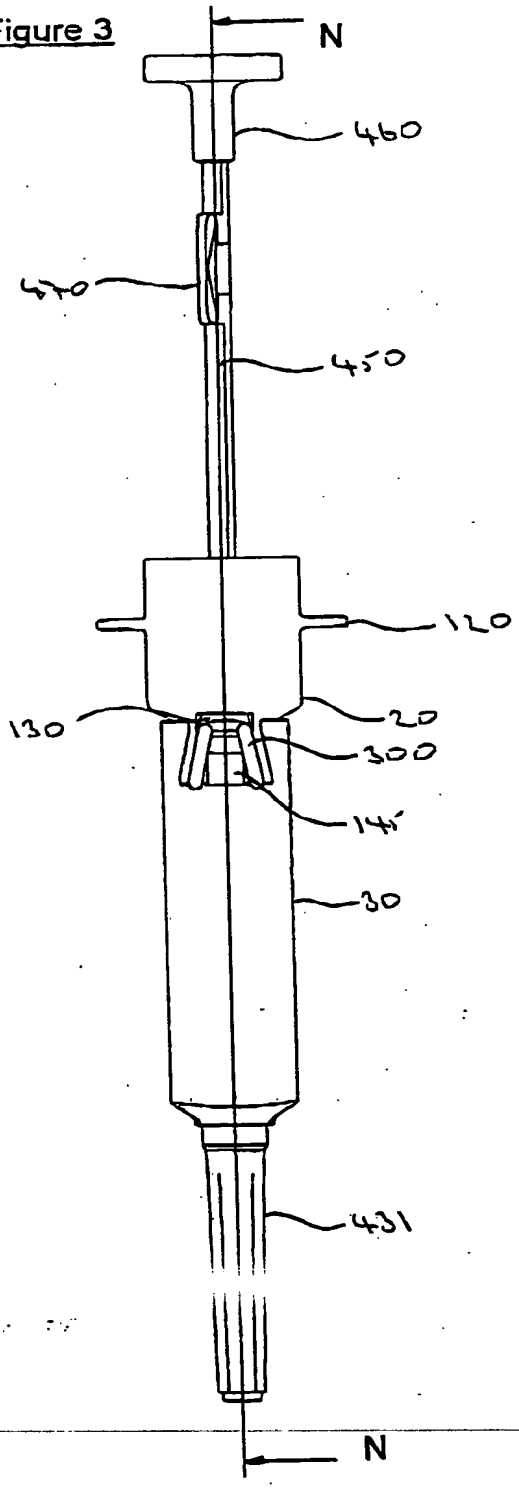

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Figure 4

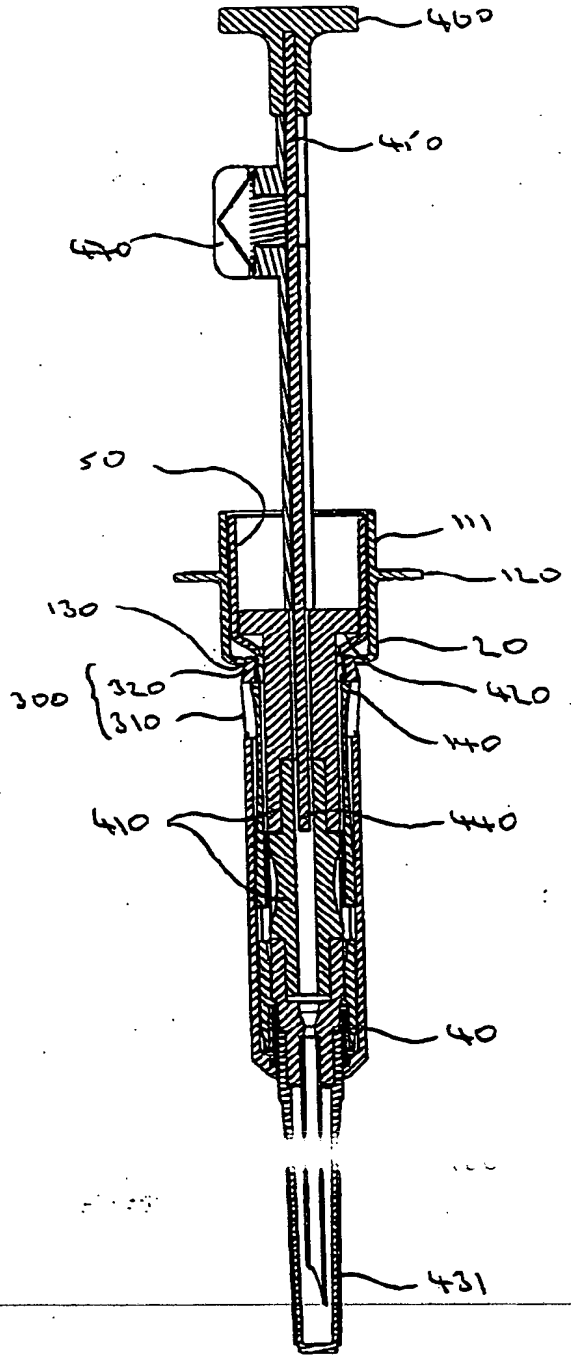

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Figure 5

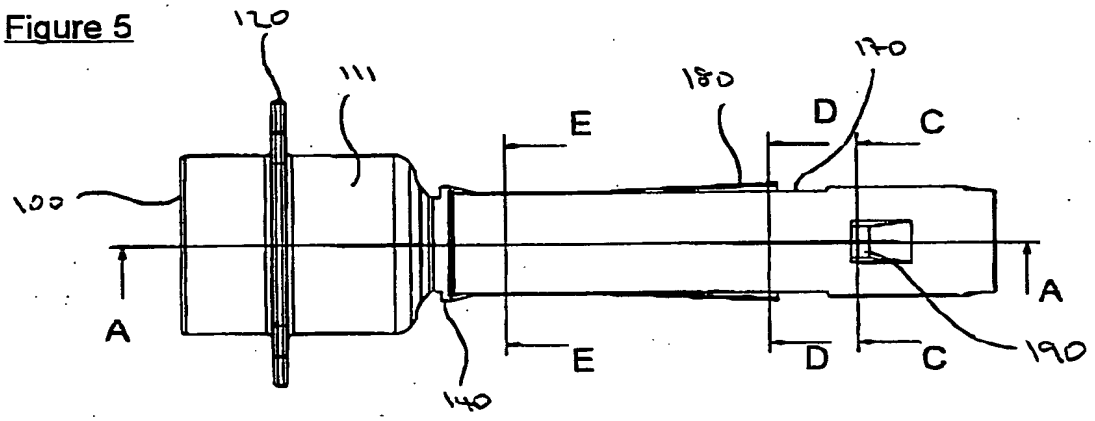

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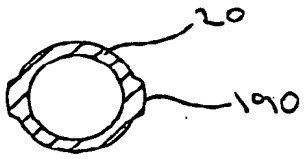
Figure 6



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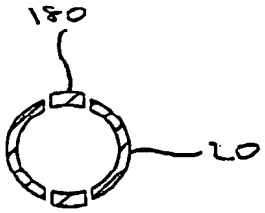

Figure 8

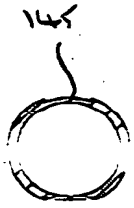

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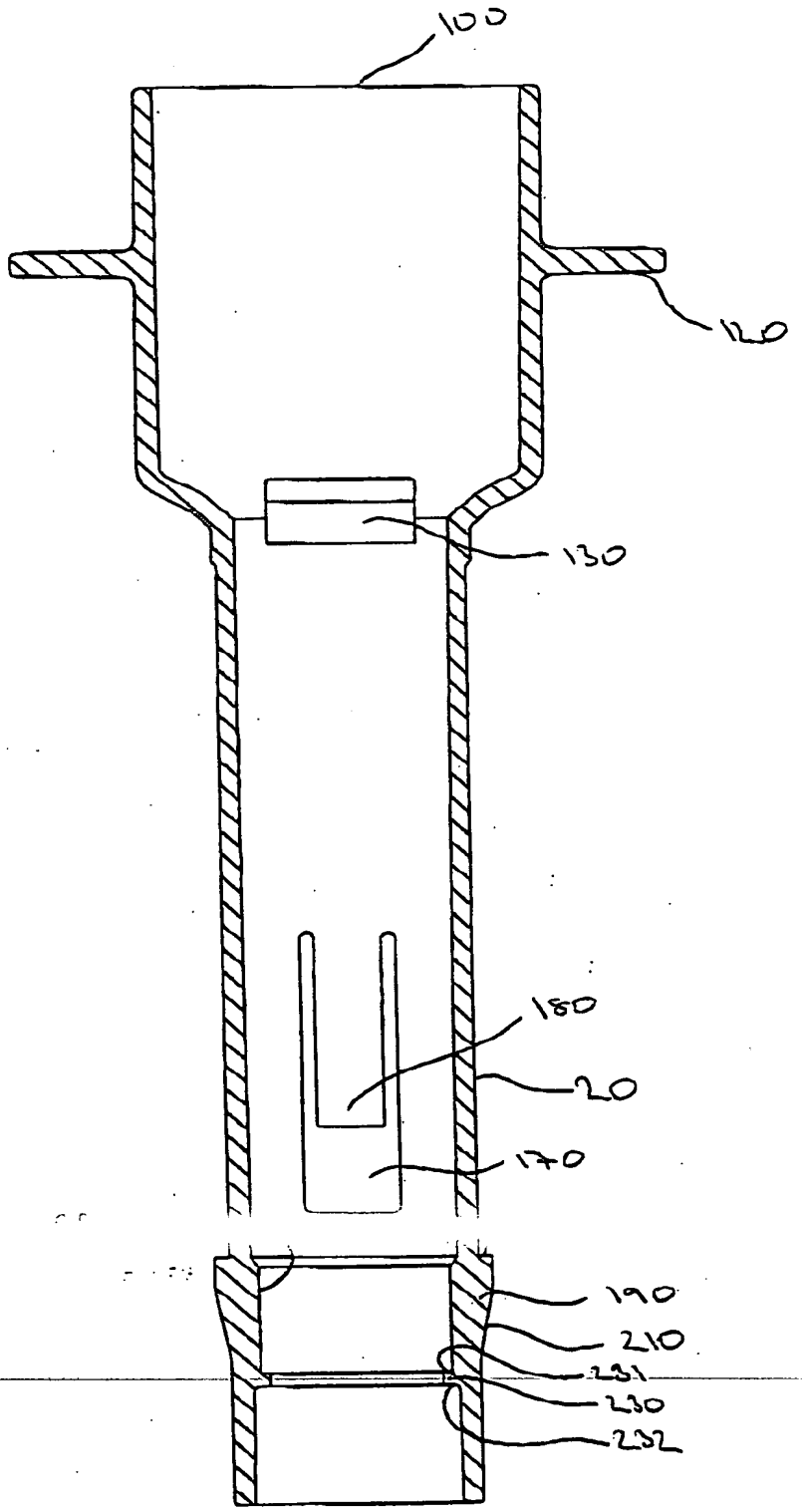
Figure 9



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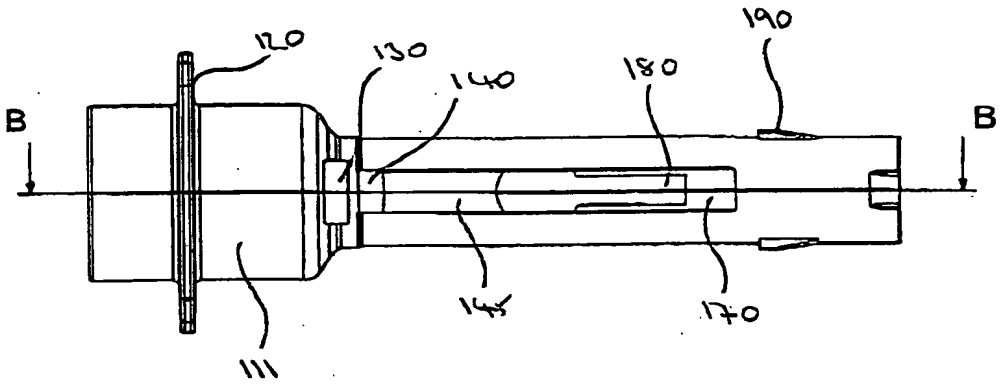

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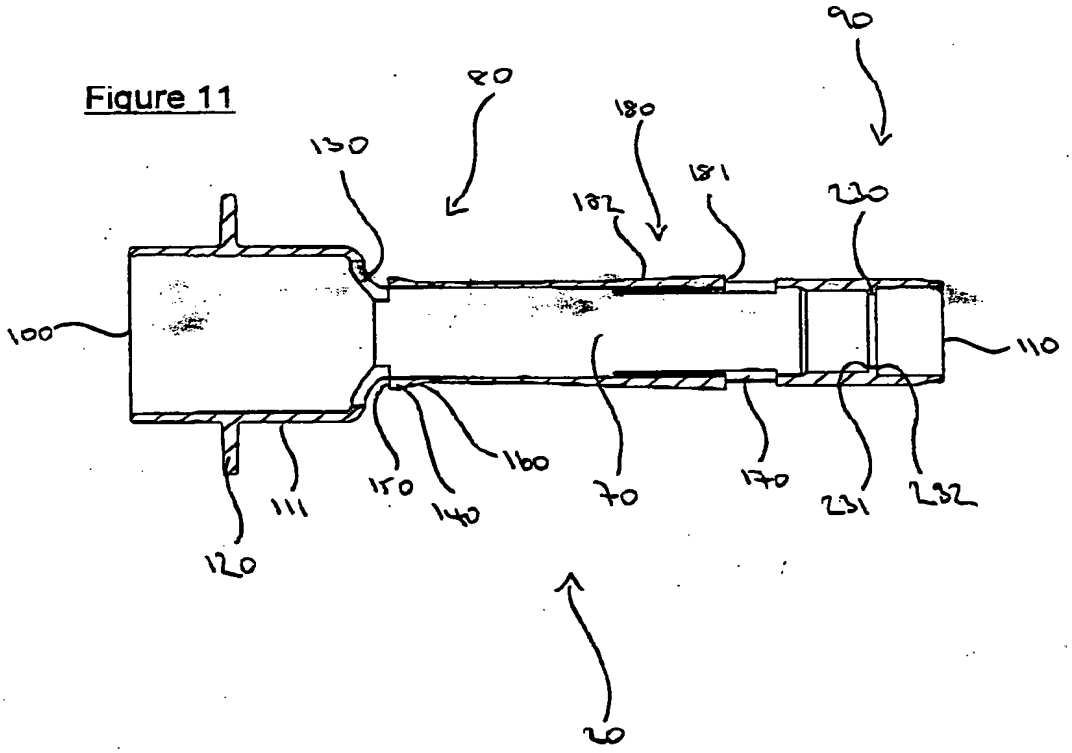
Figure 11



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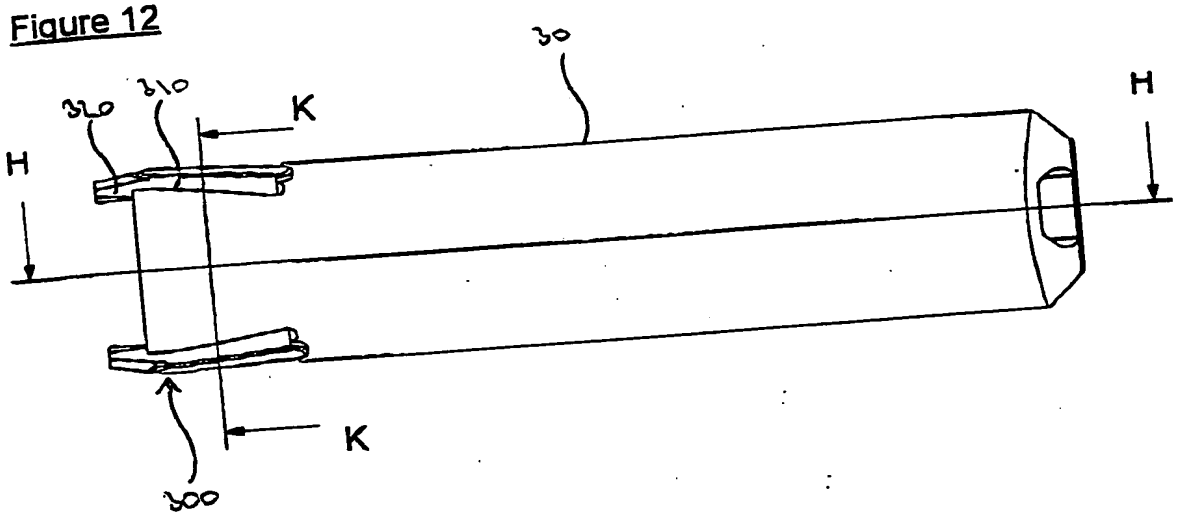

Figure 13

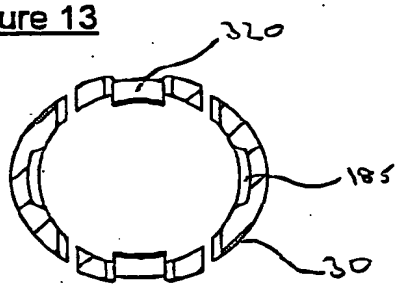

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Figure 14

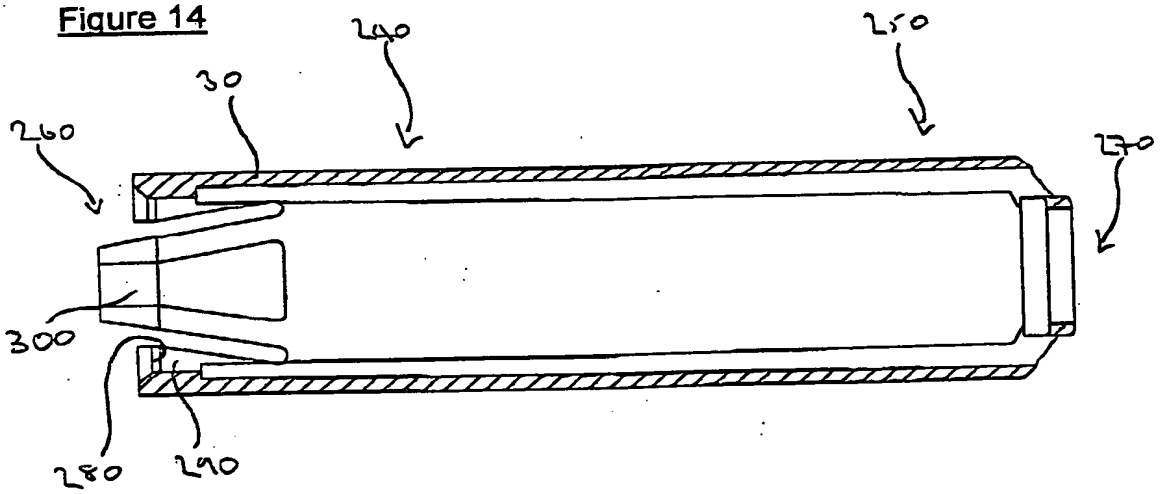
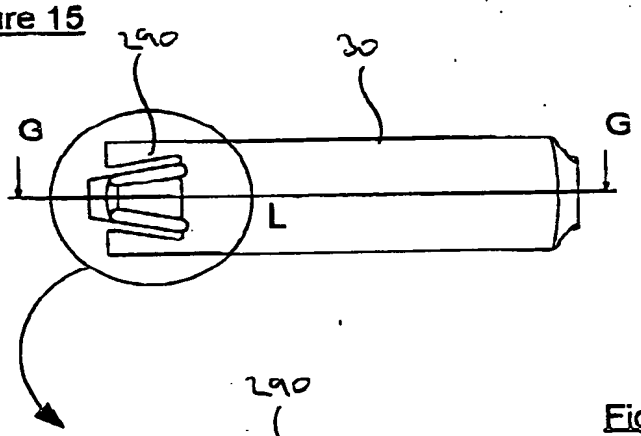


Figure 15



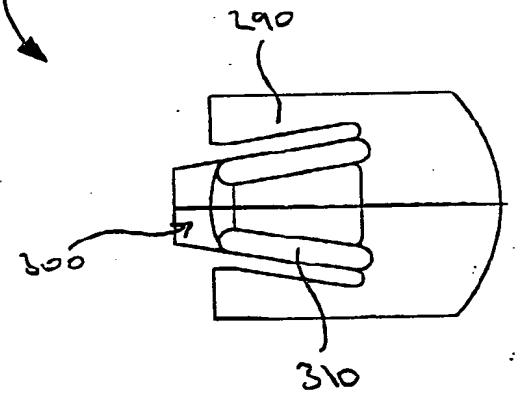
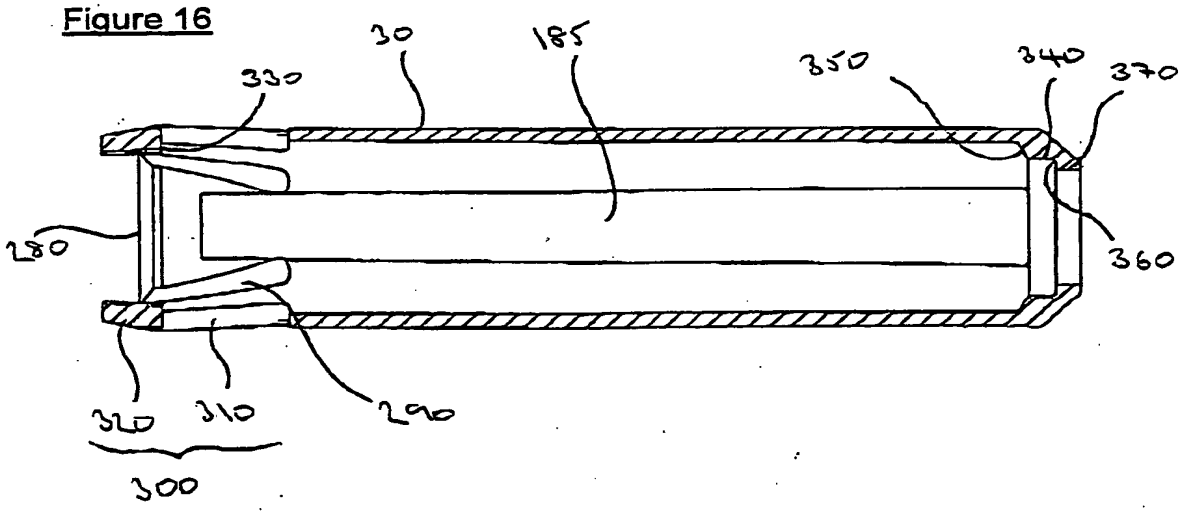


Figure 15a

Figure 16



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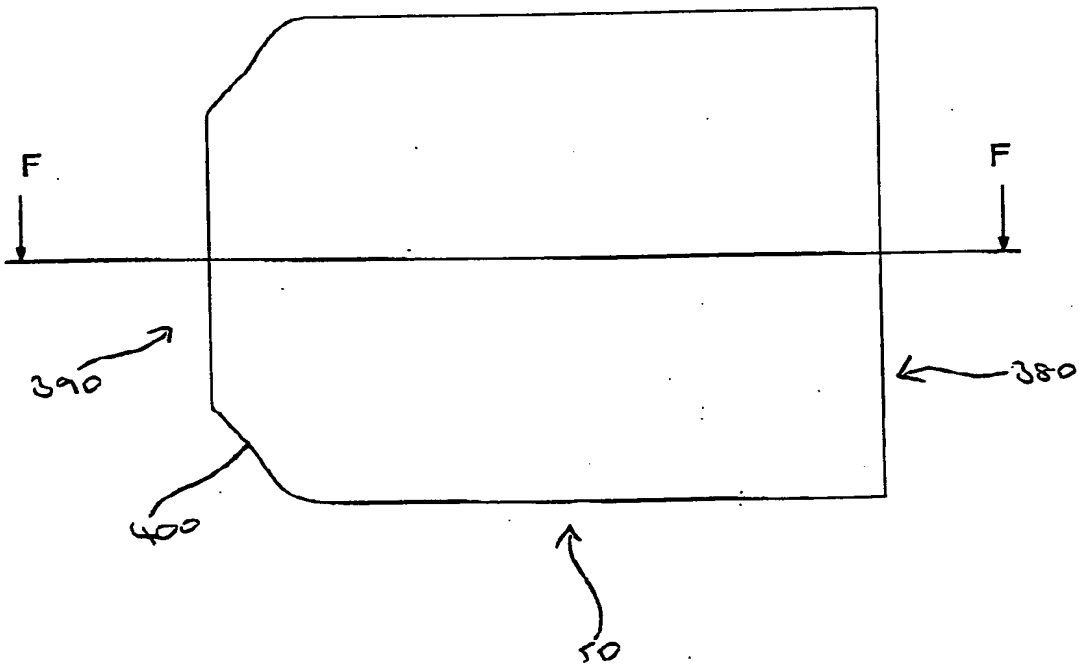
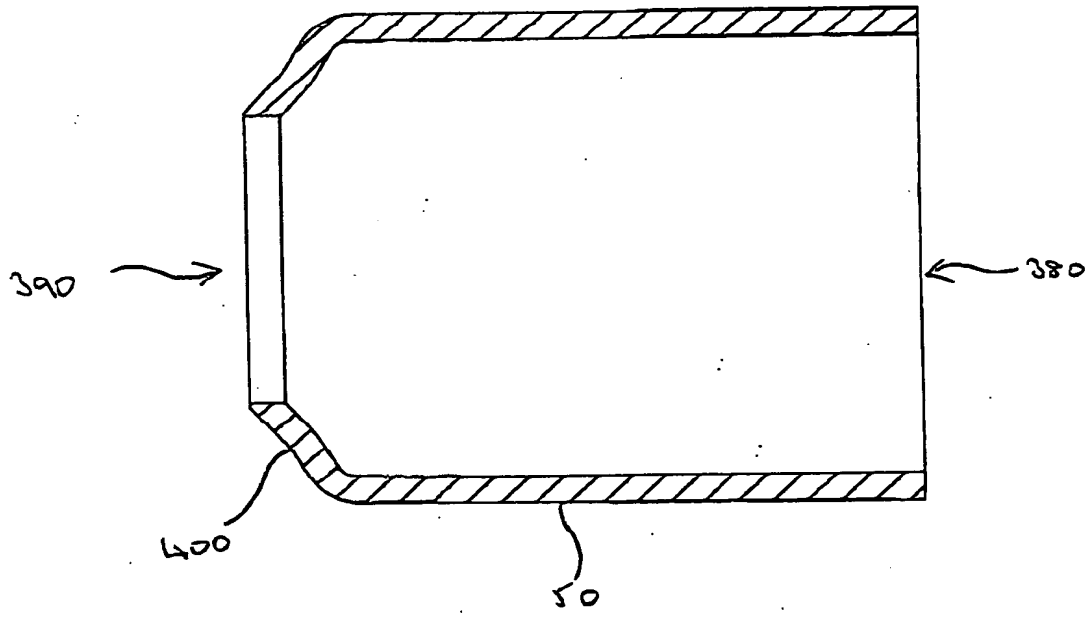


Figure 18



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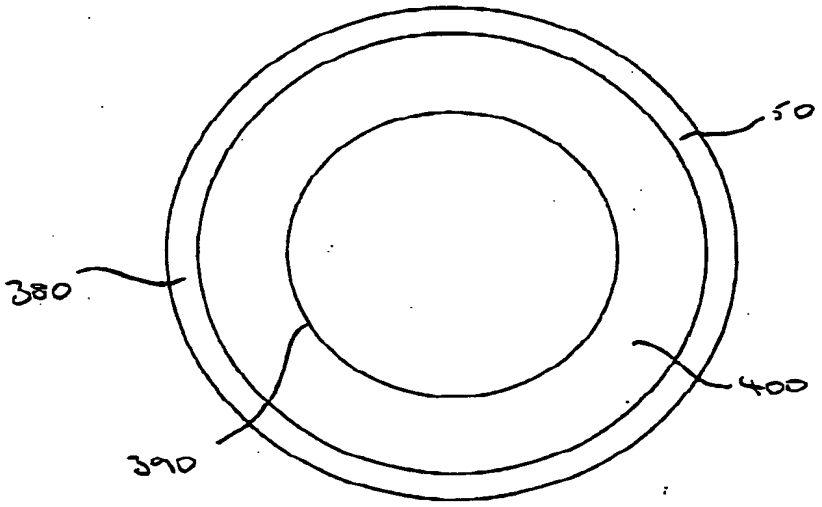

Fig.20

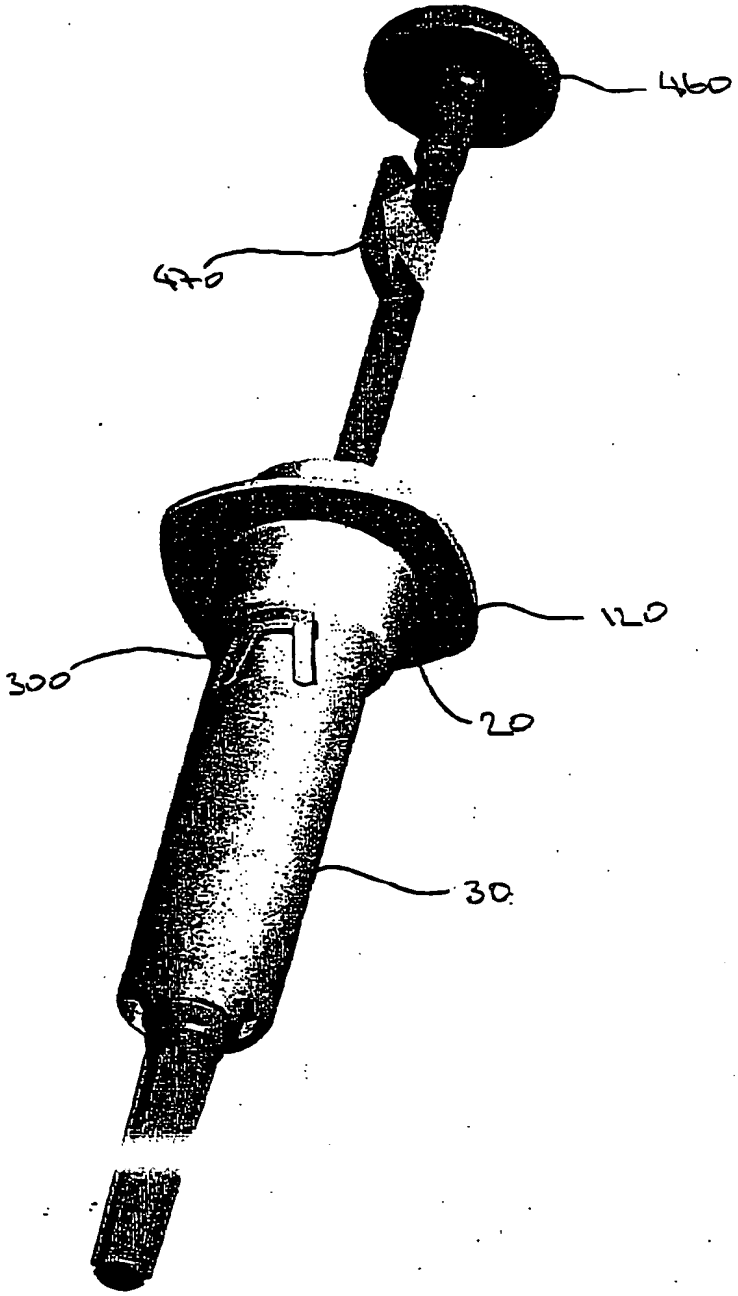

Fig. 21

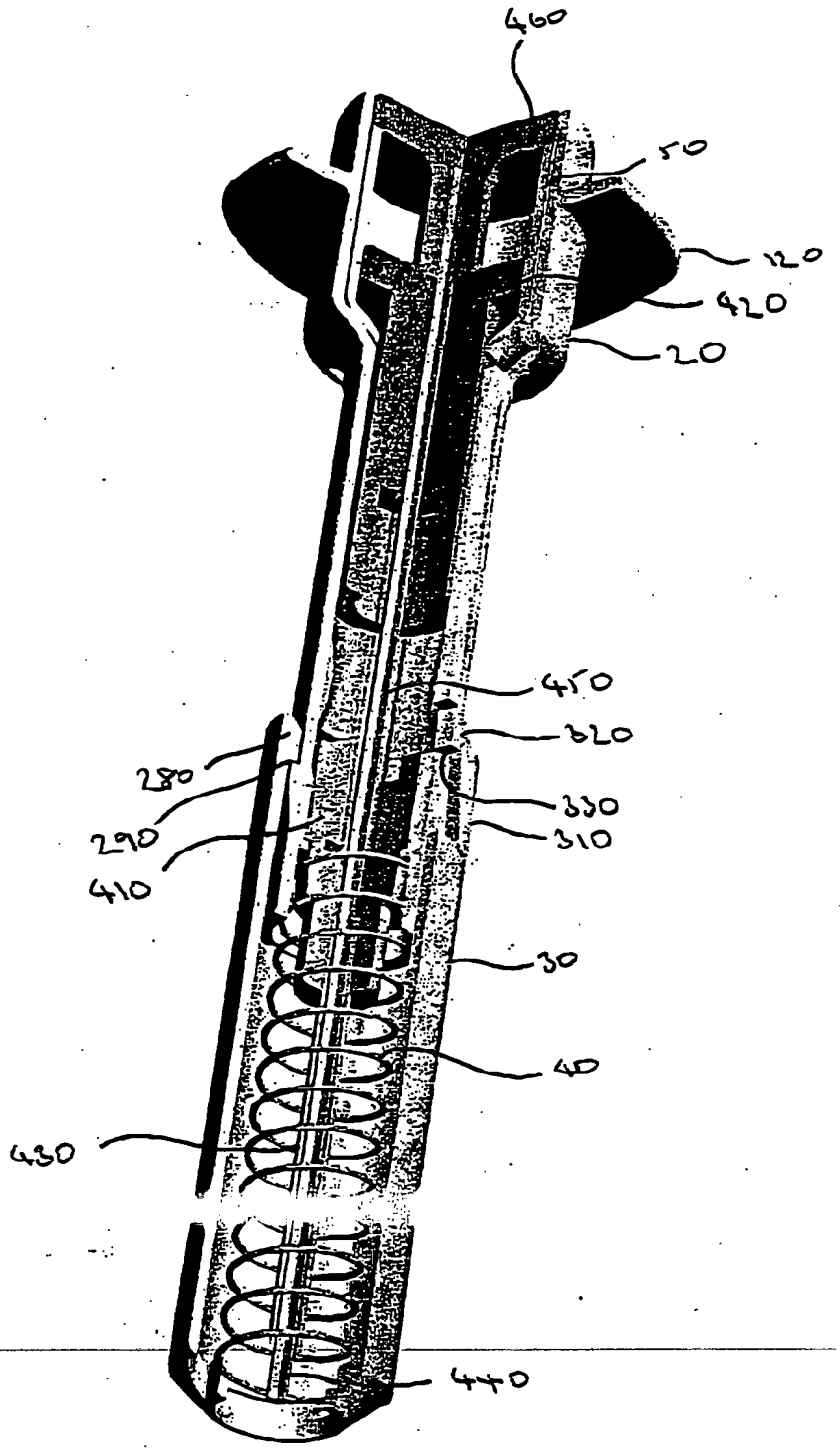

Figure 22

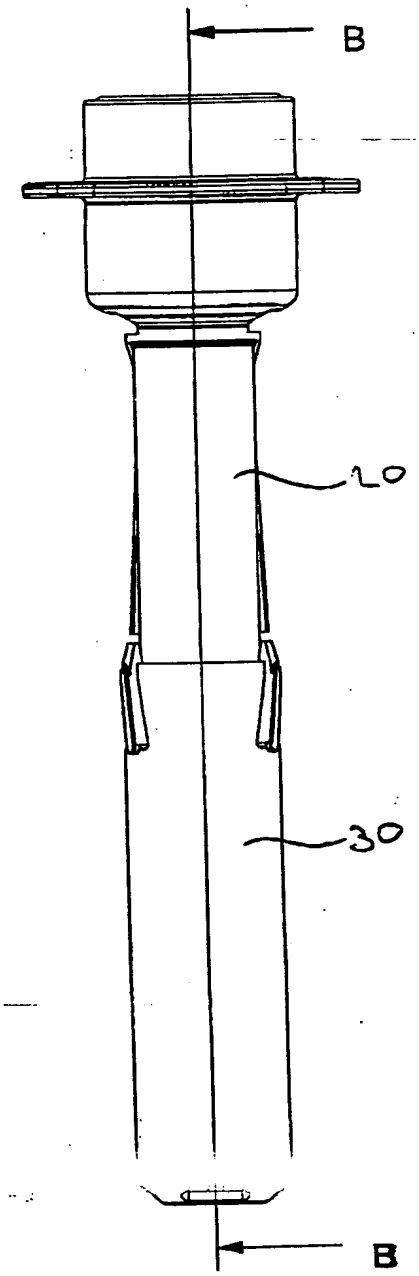

Figure 23

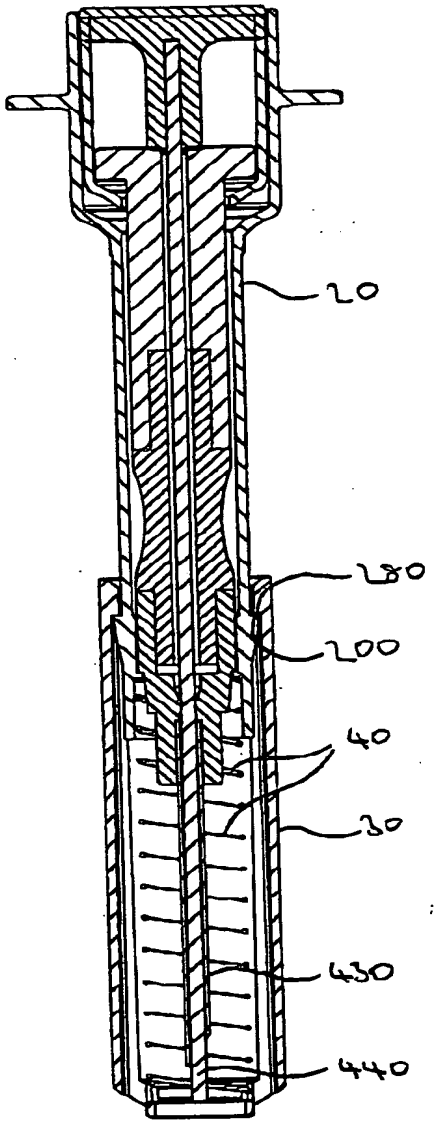

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Figure 24

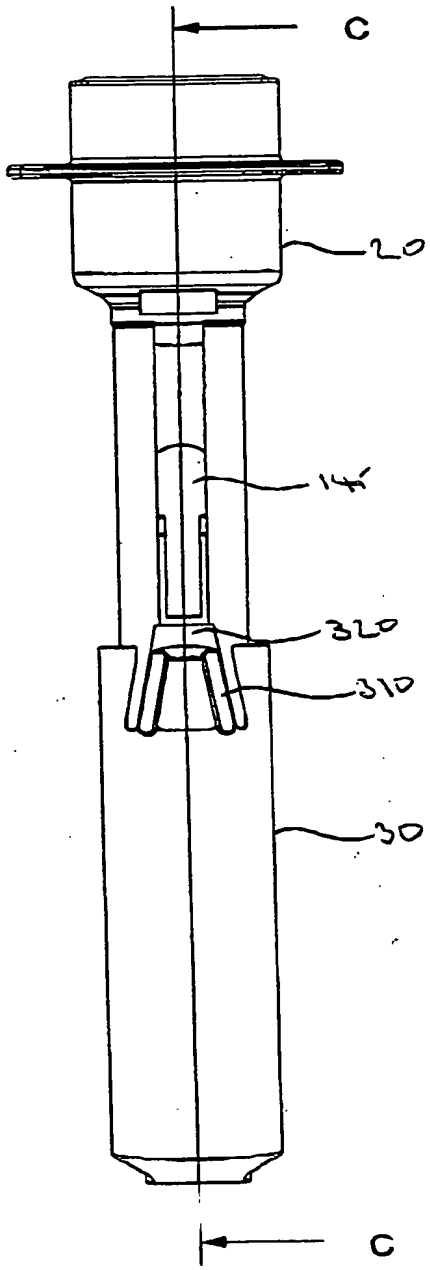

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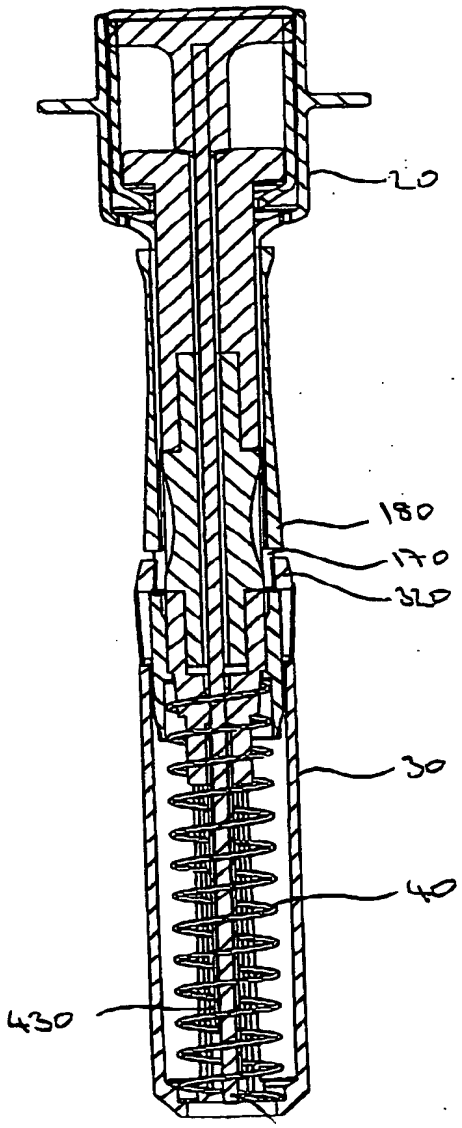
Figure 25



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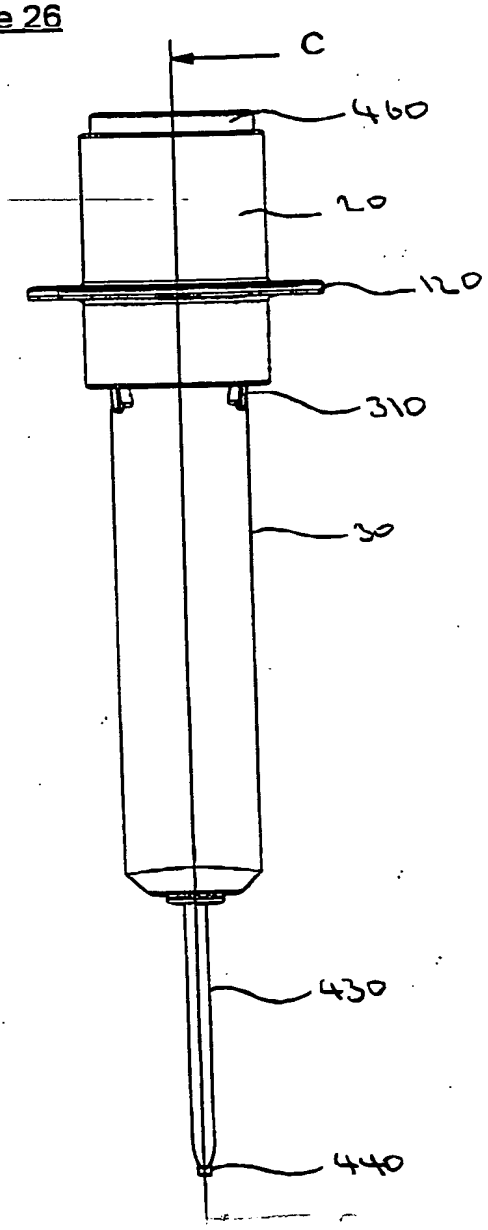

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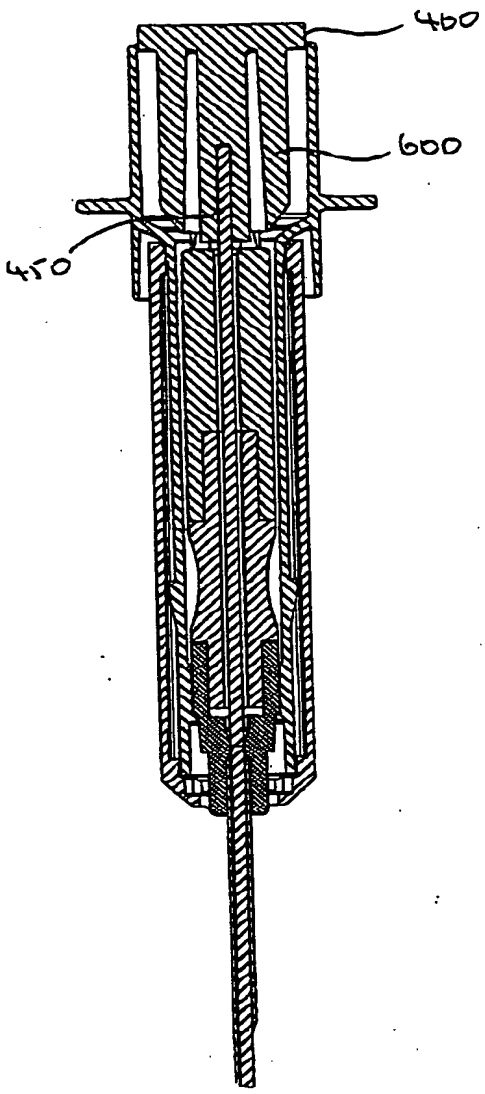
Figure 27



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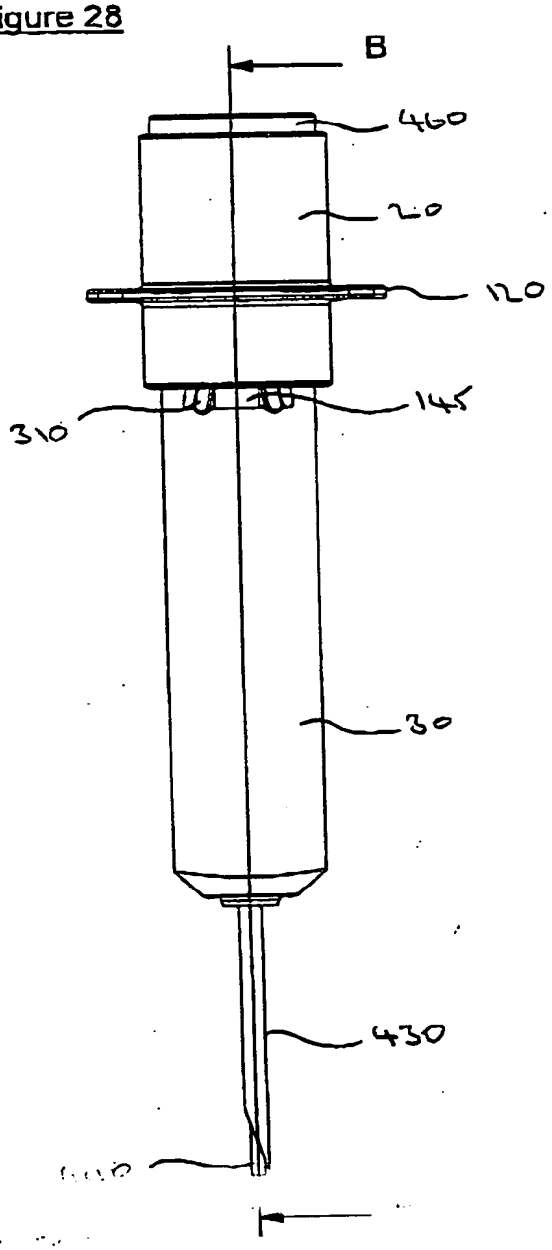

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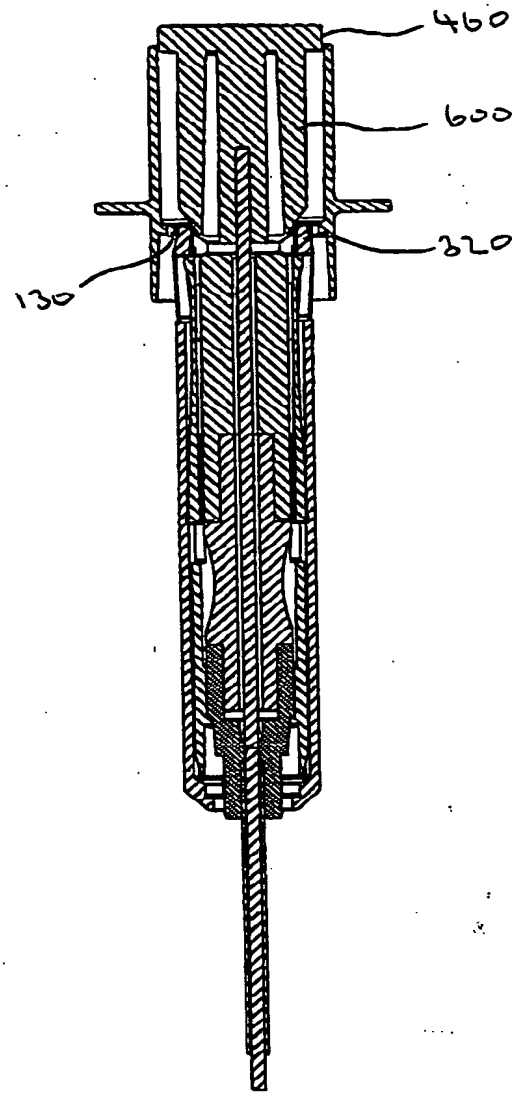

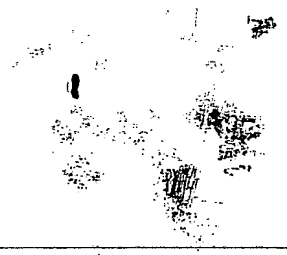

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